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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,275	01/10/2002	Karl F. Popp	19113-1-0031	8435

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	4

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,275	POPP, KARL F.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 & 3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Receipt is acknowledged of the Information Disclosure Statement (IDS) filed 04/08/02 and the IDS filed 11/26/02.

Claims 1-45 are pending. Claims 1-45 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 12, 13, 15-21, 29 and 38-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Czernielewski et al. (US Pat. No. 5,849,776).

Czernielewski discloses dermatological compositions and methods for treating dermatological conditions comprising formulations based on metronidazole or a combination of metronidazole and clindamycin, wherein the composition is intended as an anti-inflammatory treatment suitable for application by the topical route and whereby the composition can be in the form of ointments, creams, milks, powders, *impregnated*

pads, solutions, gels, sprays, lotions or suspensions (see reference column 1, line 46 through col. 2, line 48) and Abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-11, 14, 22-28 and 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czernielewski et al. (US Pat. No. 5,849,776) in view of Buseman et al. (US Pat. No. 6, 495,158 B1).

Czernielewski, as discussed above, teaches dermatological compositions and methods for treating dermatological conditions comprising formulations based on metronidazole or a combination of metronidazole and clindamycin, wherein the

composition is intended as an anti-inflammatory treatment suitable for application by the topical route and whereby the composition can be in the form of ointments, creams, milks, powders, *impregnated pads*, solutions, gels, sprays, lotions or suspensions. These compositions can be provided either in anhydrous form or in aqueous form (see reference column 1, line 46 through col. 2, line 48) and Abstract.

The composition, which is preferable for topical use, contains metronidazole at a concentration preferably of between 0.01% and 5% by weight of the total composition. This range meets the applicant's claimed range of from about 0.1% to about 2% (col. 2, lines 42-48).

The composition may also additionally contain inert or even pharmacodynamically or cosmetically active additives or combination of additives, such as wetting agents, depigmenting agents, emollients, hydrating agents such as glycerol, anti-acne agents, preserving agents and stabilizing agents, for example (col. 2, lines 53 through col. 3, line 8).

The examples at columns 3-4 demonstrate the topical anti-inflammatory activity of metronidazole and of a metronidazole plus clindamycin combination.

Czernielewski also teaches a method for the treatment of inflammation, which comprises administering an effective amount of metronidazole and a topical pharmaceutically acceptable carrier. The method of treatment comprises treatment for various skin diseases accompanied by dermatosis, such as eczema, psoriasis, acne rosacea, acne vulgaris, ulcers, and the like (col. 4, lines 53 through col. 6, line 16).

Czernielewski teaches topical administration of metronidazole whereby the composition can be in the form of ointments, creams, milks, powders, *impregnated pads*, solutions, gels, sprays, lotions or suspensions.

Czernielewski is deficient only in the sense that he does not explicitly teach the particular features of the substrate (woven, non-woven, sponge, etc).

Buseman et al. teaches an acne patch which comprises a therapeutic formulation of a topical acne drug, a solvent that dissolves the topical acne drug and a pressure sensitive adhesive whereby the patch can be made of various materials, such as woven, non-woven fabrics, natural fibers such as polyester, cotton fibers, polymeric fibers, porous films, or other kinds of matrixes and can further include antimicrobials, such as metronidazole, clindamycin and the like (see reference column 4, line 21 through col. 10, line 67); (col. 18, lines 1-30).

Therefore it would have been obvious to one of ordinary skill within the art to use the teachings of Buseman within the teachings of Czernielewski because Buseman teaches a topical therapeutic acne patch device or substrate wherein the patch is composed of various materials (i.e., woven, non-woven fabrics, natural fibers such as polyester, cotton fibers, etc.), which serve to retain the therapeutic formulation and can further include antimicrobial agents (i.e., metronidazole, clindamycin) and similarly Czernielewski teaches dermatological compositions comprising metronidazole or a combination of metronidazole and clindamycin, wherein the composition is applied by the topical route and can include such forms as ointments, *impregnated pads* and the

like. The expected result would be an improved topically administered dermatological formulation for the effective treatment of a variety of skin conditions, including, acne and rosacea.

Regarding the instantly claimed amounts or percentages of the delivery system, it is deemed obvious to one of ordinary skill in the art that suitable percentages could be obtained through the use of routine or manipulative experimentation, as these are all variable parameters.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
April 30, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600